



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,444	05/22/2002	Christian Von Falkenhausen	3868-0113 P	6939
2292 7590 08/14/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT 1618	PAPER NUMBER
			NOTIFICATION DATE 08/14/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/089,444	Applicant(s) FALKENHAUSEN ET AL.	
	Examiner Micah-Paul Young	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/21/07 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 16 recites the limitation "a substrate (5)" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1618

6. Claims 1-6,8,10,11-16 and 18-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Lehmann et al (USPN 6,306,428 hereafter '428). The claims are drawn to a rolled-up pharmaceutical laminate comprising matrix and carrier layers; wherein the layers comprise a liquid soluble adhesive that dissolves upon exposure to body fluids.

7. The '428 patent teaches a rolled up laminate formulation comprising matrix and carriers layers (Figure 3). The rolled devices comprises a core and a filmed rolled around said core (col. 1, lin. 60-65). The matrix and carrier layers comprise thickeners and cellulose derivatives (col. 3, lin. 4-10). The carrier layer comprises less water permeable materials than that of the drug-containing layer, yet also contains active agents to initiate a pulse release (examples). Along with commonly associated polymer such as polymethacrylates and other well known polymers that dissolve in gastric fluids (col. 3, lin. 65-col. 4, lin. 21). The layers further comprise an adhesive that also dissolves in body fluids (figure 3, col. 2, lin. 41-50). The rolled up device can further comprise water impermeable layers that protect the device from premature dissolution and can also comprise an active agent (col. 6, lin. 9-21). Each polymeric compound within each layer affects the delivery of the active agent. Whether the compounds are hydrophilic or hydrophobic directly affects the release kinetics of the imbedded active agents (*Ibid.*). The rolled device is prepared by first making a carrier layer, and applying an adhesive layer to said carrier layer, and allowing the composition to dry. After assembly the rolled devices are rolled into elliptical shapes, meaning the width is largest toward the center (example 2). Additional layers are added to form the laminate (col. 5, lin. 22-32; example 1-3). The diameter of the rolled device is from 0.2-1 cm (col. 6, lin. 35-44). The release profile of the active agents can be varied by changing the surface area of the device, or by changing the concentration of the

Art Unit: 1618

auxiliary polymers (examples 1-6). The rolled device, taken orally, unravels in the stomach releasing the remainder of the active agents after initial pulses of release while the device is rolled (col. 3, lin. 40-50). These disclosures render the claims anticipated.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1,7,9,11 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith et al (USPN 4,470,962 hereafter '962). The claims are drawn to a rolled-up pharmaceutical laminate comprising matrix and carrier layers; wherein the layers comprise a liquid soluble adhesive that dissolves upon exposure to body fluids and one of the layers is a pressure sensitive adhesive.

9. The '962 patent teaches a polymeric diffusion matrix that can be rolled or folded and implanted into a patient (abstract; col 9, lin. 30-38; col. 11, lin. 1-7). The laminate layers comprise polymers commonly associated in the art such as polyvinylpyrrolidone (col. 3, lin/ 7-15) and useful drugs well known in the art (col. 3, lin. 60-col.4 lin. 15). The layers comprise a concentration gradient normal to the longitudinal axis of the laminate layer, where the layers comprise pressure sensitive adhesives (col. 7, lin. 45-55; col. 9, lin. 30-37). The backing layers are composed of flexible and less soluble polyesters. These backing layers make up the outer layers of the wound and rolled device (col. 9, lin. 25-45). These disclosures render the claims anticipated.

Art Unit: 1618

Response to Arguments

10. Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608.


The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER